DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 28, 2014

Hogan Lovells US LLP
Jonathan Kahan
Columbia Square
555 Thirteen Street NW
Washington, DC 20004

Re: K142086
Trade/Device Name: NIO Adult
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: July 31, 2014
Received: July 31, 2014

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142086

Device Name

NIO Adult

Indications for Use *(Describe)*

The NIO Adult is intended to provide intraosseous access in the proximal tibia, as an alternative to IV access during emergencies. The device is for use in adult patients only.

The NIO Adult is indicated for use in providing intraosseous access as an alternative to IV access during emergencies. Humeral head access is indicated when rapid fluid or pharmacological resuscitation is required and intravenous access is not possible. The device is for use in adult patients only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

K142086

(Premarket Notification [510(k)] Number)

Applicant Name:

Company Name: Waismed Ltd.
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Date Prepared: July 31, 2014

Trade Name: NIO Adult

Classification Name: CFR Classification section 880.5570 (Product code FMI)

Classification: Class II Medical Device

Predicate Device: B.I.G. Adult Bone Injection Gun

The modified NIO Adult device is substantially equivalent to the previously cleared, B.I.G. Adult (Bone Injection Gun), also manufactured by Waismed Ltd.:

Device	Manufacturer	510(k) No.
B.I.G. (Bone Injection Gun)	Waismed Ltd.	K981853, K062940

Device Description:

The NIO Adult device is a modification to the company's cleared Adult B.I.G - Bone Injection Gun

(K981853 and K062940) to permit intraosseous access through the Proximal Tibia and the Humeral Head.

Like the cleared Adult B.I.G., the NIO Adult device is comprised of a trocar needle, spring, piston and housing. Likewise, both devices resemble a syringe and when activated, a loaded spring is released and the device injects the needle to a predetermined depth into the bone marrow cavity.

The difference between the NIO Adult device and the cleared B.I.G. device is primarily the safety latch and trigger mechanism which is designed to provide a safer device and the minor design modifications to the plastic housing and needle dimensions in order to accommodate the modified safety mechanism.

Intended Use/Indication for Use:

The NIO Adult is intended to provide intraosseous access in the proximal tibia, as an alternative to IV access during emergencies. The device is for use in adult patients only.

The NIO Adult is indicated for use in providing intraosseous access as an alternative to IV access during emergencies. Humeral head IO access is indicated when rapid fluid or pharmacological resuscitation is required and intravenous access is not possible. The device is for use in adult patients only.

Performance Data:

Provided performance data include a Trigger Safety Mechanism Test, Needle Stabilizer (Mechanical Stopper) Performance Test, Needle Penetration Depth Test, Compressed Spring Force Test, Bone Fracture Test, Biocompatibility Testing (per ISO 10993-5 -10, and -11), Hub-Cannula/Hub-Needle Bond Strength Testing (According to ISO 7864), and Structural Deformation and Needle Integrity Test.

Substantial Equivalence:

The intended use and technological characteristics of the modified NIO Adult device are substantially equivalent to the intended use and technological characteristics of the original B.I.G. Adult device.

The addition of a second safety mechanism only improves device safety and does not raise new types of safety or effectiveness questions. Device testing demonstrates that the device functions as intended and inserts the needle to the same penetration depth as the predicate device.

Conclusions:

Based on the performance testing and comparison to the predicate device, the modified NIO Adult device is substantially equivalent to the B.I.G. Adult predicate device.